Official Title: Improving Adherence in Adolescents and Young Adults With Bipolar Disorder (IGNITE)

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UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES
(v. 01.2019)

Project Title: Improving Adherence in Adolescents and Young Adults with Bipolar Disorder - RCT

Principal Investigator: Martha Sajatovic, MD

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?
You are being asked to participate in a research study because you are an adolescent or young adult (age 13-21), have been diagnosed with bipolar disorder, and have missed some doses of your medication in the past week or month.

Things I should know about a research study
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Introduction/Purpose
The purpose of this research is to find out if an educational and behavioral intervention, called Customized Adherence Enhancement for Adolescents and Young Adults (CAE-AYA), helps patients with taking their medication and missing fewer doses compared to a standard educational program about bipolar disorder.

You will be one of 40 participants enrolled in this study which includes 2 sites in Ohio. Approximately 20 participants from CWRU/UH and approximately 20 participants from the University of Cincinnati will participate in this study.

Key Study Procedures
We expect that you will be in this research study for about 6 months. During that time you will be asked to complete 5 study assessment visits and 5 educational session visits (4 over 4-6 weeks and then one more about 4 weeks later). Members of the study staff will also call you about 2 weeks after the fourth educational session.

More detailed information about the study procedures can be found under “Detailed Study Procedures.”

Key Risks
It is possible that some of the questions you are asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it

and go to the next question. You may also feel tired after completing all the questionnaires. More detailed information about the risks of this study can be found under "Detailed Risks."

Benefits
We cannot promise any benefits to you or others from your taking part in this research. However, you may find it helpful to participate in the educational sessions.

Alternatives to Study Participation
Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Detailed Study Procedures:
As a participant in this study, you will be asked to come to the W.O. Walker Center. Your participation in this study will last for about 6 months and will involve 5 study assessment visits and 5 educational session visits (4 over 4-6 weeks and then one more about 4 weeks later). Members of the study staff will also call you about 2 weeks after the fourth educational session. If you are not able to come in for a visit at the W.O. Walker Center you may be able to complete study assessment visits and educational session visits over the internet or by phone.

If you agree to participate in this research, we would ask you to do the following things (you may refer to the Study Schedule of Events on the next page):

Screening
At this visit, the following screening procedures will be performed to determine if you can take part in this study:

- you will sign the informed consent form
- you will receive a psychiatric diagnostic assessment
- you will be asked basic demographic questions about facts such as your age and gender
- you will be asked questions about your attitudes, psychiatric symptoms, and how you are taking your medication
- you will be given a special pill box (SimpleMed) to place you bipolar medication in
    - you will be asked to bring in the SimpleMed box at each visit

The screening visit will last about 120 minutes or 2 hours.

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Study Schedule of Assessments and Events

Procedure	Screen	BL	Session 1	S2	S3	S4	Call	Booster	Visit 1	V2	V3*
Visit Timing	Day -21 to -7	Day 0	Week 0 to Week 6				S4 + 2 to 4 weeks	S4 + 4 weeks		V1 + 4 weeks	V2 + 12 weeks
Informed Consent	X										
Diagnosis: SCID	X										
Demographics	X										
Adherence vulnerability assessments	X	X							X	X	X
Treatment adherence measures	X	X							X	X	X
SimpleMed Box	X	X							X	X	X
Psychiatric symptom ratings	X	X							X	X	X
Quality of Life questions		X							X	X	X
Health Resource Use questions		X							X	X	X
Adherence Barrier questions		X							X	X	X
Attitude and Behavior questions		X							X	X	X
Randomization to intervention		X									
Provider notified of enrollment		X									
Intervention Visits			X	X	X	X		X			
Telephone Follow-up Call							X				
Acceptability/Satisfaction questions									X		

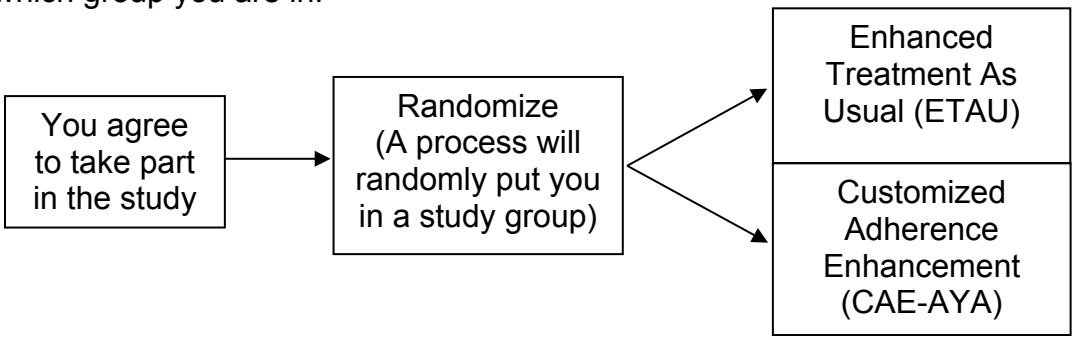
* Individuals who terminate study prematurely will have termination study assessments done at the time that termination occurs

Baseline
At the baseline visit, you will be asked questions about your attitudes, psychiatric symptoms, and how you are taking your medication. You will be randomized to either the CAE-AYA or ETAU intervention.

We will also ask you to complete a release of information so we can provide the doctor who prescribes your medications for bipolar disorder the reasons why you may not be taking your medications. This could help you and your doctor continue to discuss these after you complete the study. When you end study, we will also ask them questions about their impressions of the intervention.

The baseline visit will last about 90 minutes.

Randomization/Study Intervention
If you participate in this study, you will be assigned to a study group by chance using a process similar to the flip of a coin. This process is called randomization. Neither you nor study staff will select the group to which you will be assigned. The study staff will let you know which group you are in.



Educational Intervention Sessions:
There will be four (4) in person sessions over 4-6 weeks. During those sessions you will meet with a member of the study team and you will receive either the study's educational and behavioral intervention (CAE-AYA) or a standard educational intervention (ETAU) depending on which group you were randomized to. During the session, you will receive information on how to deal with your condition and take your medications, and will be able to ask questions. About four weeks after the fourth session you will have an additional session. All intervention sessions will be audio or video recorded.
Each session will last about 60 minutes.

Follow up assessment visits
After you have completed the Educational Sessions you will return for assessment visits that will be similar to the Screen and Baseline visits. At Visit 1, Visit 2, and Visit 3, you will be asked questions about your attitudes, psychiatric symptoms, and how you are taking your medication.

Visit 1, Visit 2, and Visit 3 will each last about 60-90 minutes.

Detailed Risks
Your participation in this study does not involve any physical risk to you.
Some of the activities we will ask you to complete might make you feel uncomfortable. You may refuse to answer any of the questions, take a break, or stop your participation in this study at any time.

The possible risks and/or discomforts associated with the procedures described in this study include:

- Although your condition may improve during the study, it is also possible that your condition may worsen during the study. Your regular mental health care provider as well as your other regular care providers will continue to monitor your condition while you are in the study. Regardless of whether or not your condition improves or worsens while you are in the study, your regular care providers and you will continue to make decisions about your care such as medication changes and dose adjustments. These decisions may or may not include withdrawal from the study.
- Should your condition unexpectedly worsen and you report to any of the study staff plans to harm yourself, for your own safety you may be evaluated by the principal investigator or another mental health professional for possible hospitalization.

There is a risk of breach of confidentiality which means that someone who is not listed in this form might view your data either by accident or from malicious actions they take to hack the data. We are protecting against this by only storing information that can be directly linked to you on UH computers, in password protected files which are behind firewalls.

Consequences of Withdrawing or being discontinued from the Research
The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study requirements
- If the study is stopped by the sponsor, Institutional Review Board (IRB) or FDA.

If you withdraw from the study prior to its completion, you will be asked to return the SimpleMed pill box and if possible, come in for a final clinical visit to complete the Visit 3 procedures listed in the Study Schedule above.

Financial Information

There is no cost to you or your insurance for participation in this study.

You will receive $25 for each assessment visit you complete. There are 5 assessment visits. You will also receive an additional $10 when you return the SimpleMed pillbox at the end of the study. Total compensation for participation in this study is up to $135. If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits that you have completed. Payment will be made by check mailed to you after the meeting is completed. If you do not have a bank account to cash the check, the research assistant will discuss alternate payment methods with you.

You will also receive assistance with transportation to each of the assessment visits and the intervention visits in the form of a bus pass or parking pass.

In addition, if you are randomized to the educational and behavioral intervention (CAE-AYA), you may be given small items (e.g., $5 gift card, pens, notebooks, key tags, lanyards, mini calendars, etc.) for meeting goals you set during the sessions.

To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS. You will be issued a 1099-Misc form only if payment exceeds $600 from all studies in which you are participating, in a fiscal year.
If the SimleMed pillbox should get lost or break, please let the study team know as soon as possible. You will not be responsible for the cost.

Contact for Future Research

Our study team may have additional research studies in the future. We would like your permission to contact you in the future if we think you could be a potential participant in one of our studies. Please check one of the boxes below that indicates your choice to be contacted for future research.

- ❑ Please contact me by _____ for future research opportunities.
- ❑ Please do not contact me for future research opportunities.

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Permission to Contact Parent or Caregiver

Our study team may want to ask your parent or a caregiver how you are doing with taking your medication at 4 times points throughout the study. Please check one of the boxes below that indicates whether or not we can contact them.

- ❑ Yes, you can ask my parent or a caregiver how I am doing with taking my medication.

- ❑ Please do not contact my parent or a caregiver.

Clinical Trial Information

U.S. NATIONAL INSTITUTES OF HEALTH (NIH) CLINICAL TRIAL DATABASE: A description of this clinical trial will be available on **http:///www.clinicaltrials.gov**, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time to find out information about the trial and basic results.

Student/Employee Rights

If you are a students or employee Case or UH, choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor will the results be shared with your supervisor.

Confidentiality

The records of this research will be kept confidential. Any time information is collected, there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

In any sort of report we might publish, we will not include any information that will make it possible to identify a participant. Research records will be kept in a locked file and access will be limited to the researchers, the institutional review board responsible for protecting human participants, and regulatory agencies.

The only exception to this promise of confidentiality is that we are legally obligated to report evidence of child abuse or neglect.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Data without any identifiable information may be shared with our collaborators on this study and the University of Cincinnati, Cincinnati Children's Hospital Medical Center, and the University of Florida.

All videotapes, audiotapes, and photographs will be destroyed at the end of the study. You will be asked to sign a separate consent form called GM-23 that allows us to use this information. If you do not agree to being recorded and sign the GM-23, the investigators will need to determine whether you will be able to participate in the study or not.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for

a research study entitled "Improving Adherence in Adolescents and Young Adults with Bipolar Disorder – Advisory Board" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Martha Sajatovic, and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you:

- your name, initials, address, telephone number, date of birth and other demographic information;
- your medical history (including the history and diagnosis of your disease and your family medical history) and the name of your physician(s) and locations where you received any treatment;
- information about other medical conditions that may affect your participation, including information relating to mental health, behavioral health and psychiatric disorders; and alcohol and drug dependence or abuse;
- specific information about any treatment/therapy you receive while participating in the research study and treatment you received prior to the research study (including treatments and therapies, surgeries, hospitalizations and medications);
- information about how frequently you take your medications;
- information about your general health status and the status of your disease or medical condition; and
- numbers or codes that identify you such as your social security number, medical record number, and research study case number.

This PHI will be used to help with refining the CAE intervention. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Case Western Reserve University, including staff from the Department of Psychiatry and Department of Neurology; University Hospitals, including the staff from the Department of Psychiatry, other staff from the Principal Investigator's medical practice group, the Center for Clinical Research and the

Law Department; and Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to:

Martha Sajatovic, M.D., Department of Psychiatry – 7th floor
Case Western Reserve University, 10524 Euclid Ave., Cleveland, OH 44106

If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center

(UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Martha Sajatovic can also be contacted at 216-844-2400. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research-related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Associate Chief Scientific Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

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x	
Signature of Participant	Date/Time
x	
Printed name of minor if used to obtain assent	
x	
Signature of Parent/Legal Guardian (if participant under 18 years of age)	Date/Time
x	
Printed name of Parent/Legal Guardian	
x	
If Legal Guardian, indicate relationship to child	

Study personnel (only individuals designated on the checklist may obtain consent)

x	
Signature of person obtaining informed consent	Date/Time
x	
Printed name of person obtaining informed consent	